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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,077	09/19/2000	Michael Climo	7732-020-27 DIV	5645

7590 07/28/2005

Steven B Kelber
PIPER MARBURY RUDNICK & WOLFE LLP
1200 19th Street N W
Washington, DC 20036-2412

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/665,077

Applicant(s)

CLIMO ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5,8-11 and 25-49 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 35-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5,8-11,25-27,29-34,49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Claims 3-5,8-11;25-49 are pending.

Response to restriction requirement filed 05/06/2005 is acknowledged. Applicant elected, with traverse, Group I, claims 3-5,8-11,25-27,29-34,49¹. Applicant argues that the search will not be burdensome, but failed to provide arguments why the search would not be burdensome. Therefore, the restriction requirement is still deemed proper and is therefore made FINAL. Claims 28,35-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 28,35-48 is requested.

With respect to election of species, applicant elected penicillin as species of lactam antibiotic.

Claim Rejections - 35 USC § 102

2. Claims 3-5,8-11,25-27,29-34,49 are rejected under 35 U.S.C. 103(a) as being obvious over Climo et al (US 6,028,051) in view of Polak et al. (Diagn. Microbiol. Infect. Dis., 17, 265-270, 1993) and Schaffner et al (Yale J. Biol. Med., 39, 215-229, 1967; the reference was used in the previous rejections).

The applied reference has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

Art Unit: 1631

by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

6,028,051 patent teaches method of treating staphylococcal infection using lysostaphin, or analogs thereof, and another antibiotic. Lysostaphin can be used at dosages from 50 to 2000 mg/kg and administered either in a single dose or as continuous administration for up to 14 days (col. 6, lines 20-25). Besides lysostaphin, other naturally occurring enzymes of this type that retain proteolytic ability of proteolytic attack against glycine-containing bridges in the cell wall of staphylococci can be used (col. 4, lines 21-48). Lysostaphin can be administered, as a part of combinatorial therapy, prior to or simultaneously with one or more antimicrobial agents (col. 3, lines

¹ Examiner apologizes for errors in the designation of claims to Groups I and II. Proper numbers of claims are cited herein.

Art Unit: 1631

59-69). The administration of the antibiotics can be done by any of conventional ways (col. 4, lines 57-64).

The reference does not use of penicillin, which is an elected species of the second antibiotic in the instant application. Combining lysostaphin and penicillin in a combinatorial therapy is known in the art. Thus, Polak et al tested antibiotic effect of lysostaphin alone or in combination with various β lactam antibiotics. In *in vitro* experiments both lysostaphin and a second antibiotic were effective in inhibition several staphylococcus strains (Table I). When combined lysostaphin and a second antibiotic (selected from penicillin, methicillin, cephalosporin B, vancomycin, gentamicin, etc) produced additive or synergistic effects. See abstract and Tables 2-5. The reference suggest therapeutic potential in using combination of lysostaphin with a β -lactam antibiotic (see Discussion). Further, Shaffner et al teach that in the cases of strains having reduced sensitivity to lysostaphin, sensitivity to penicillin increase. See pages 224-225.

Thus, it would be *prima facie* obvious to one skilled in the art to be motivated to use penicillin as a part of combinatorial therapy because Polak et al or Shaffner et al teach that combining lysostaphin and a second antibiotic, such a penicillin produces additive or synergistic effects, which is a desired effect for treatment of an infection.

With respect to the dosage of penicillin, it would be obvious to select an appropriate amount of the second antibiotic as a part of routine optimization.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 3-5,8-11,25-27,29-34,49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.6,569,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 6,569,830 are directed to pharmaceutical composition comprising lysostaphin and a lactam antibiotic (such as penicillin, cephalosporin, etc) taken in the same amounts as instantly claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D, can be reached on (571) 272-0718. The fax phone

Art Unit: 1631

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.



Primary Examiner

Art Unit 1631

mlb